

REMARKS

Claims 1, 2 and 4-20 are pending. Of these claims, claim 8 has been amended and claim 9 has been cancelled. Support for the claim 8 amendment may be found in Example 6 of the application, which recites that distillation was performed in a distillation unit composed of a thin film evaporator connected to a rectification column (a type of fractionating column) and that the distillation conditions included a heater temperature in the range of 240° C to 270° C. Accordingly, the amendments do not add new matter. Reconsideration of the application in view of the amendments and the following Remarks is respectfully requested.

35 U.S.C. §103(a) Rejection Based on Ghisalberti in view of Saebo et al.

Claims 1, 2 and 4-7 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Ghisalberti (WO2001/18161) in view of Saebo et al. (U.S. 6,410,761). According to the Office Action, Ghisalberti discloses a process for the preparation of conjugated linoleic acid (CLA) and further discloses that the CLA can be refined by conventional refining techniques, such as vacuum distillation, in order to obtain high grade CLA. (Office Action at page 5.) The Office Action further suggests that the conventional refining techniques disclosed in Ghisalberti result in an enriched product. (Office Action at page 6.) According to the Office Action, it would have been obvious to use conventional refining techniques, such as vacuum distillation, as disclosed by Ghisalberti to obtain a product stream enriched in desirable CLA isomers as claimed in the present claims. Saebo is cited as disclosing that a distillation pressure between 0

and 760 mmHg can be used in a distillation process to purify CLA. Reconsideration of the Examiner's rejection in view of the following remarks is respectfully requested.

The present claims recite a process for producing a refined conjugated linoleic acid containing material which is enriched in desirable c9,t11, t10,c12 isomers of the esters of conjugated linoleic acids. The claimed process recites distilling a first ester stream containing desirable c9,t11 and t10,c12 isomers of the esters of conjugated linoleic acids to increase (enrich) the content of these desirable isomers in the final product stream. In addition, the distillation process removes side products formed during the conjugation process.

Surprisingly, the applicant has discovered that conjugated linoleic acid esters can be distilled under certain conditions, utilizing a fractionating column and a heater operated at a temperature in the range of 240° C to 270° C, to obtain an increase in the amount of desirable isomers of conjugated linoleic acid esters, while minimizing the formation of undesirable side products and rearrangement of undesirable isomers. Previously it was believed that conjugated linoleic methyl esters were too thermally unstable to be distilled using high temperature (above 220° C) distilling techniques and that only extremely short time purification techniques, such as molecular distillation, at lower temperatures could be used to purify conjugated linoleic acid materials. See, Saebo U.S. Patent No. 6,410,761 at Col. 10, lines 26-35.

The newly cited Ghisalberti reference relates to processes for preparing CLA. According to the reference, high grade CLA can be obtained by further refining the CLA product by "conventional refining techniques including drying under vacuum, clarification

by bleaching earth, stripping as vacuum distillation techniques or the like, to provide a purified, odourless and tasteless CLA." Ghisalberti reference at 7-8. According to the Office Action, this passage in Ghisalberti renders obvious the use of any known distillation means to refine and enrich a CLA ester. This position is respectfully traversed.

The optional refining disclosed by Ghisalberti relates to the deodorization of the final product and in no manner teaches or suggests enriching the product stream with the desired CLA isomers, via a fractionation column and a heater, as required by the present claims. The phrase "stripping as vacuum distillation techniques or the like, to provide a purified, odourless and tasteless CLA" clearly indicates to one skilled in the art that vacuum stripping can be used to deodorize CLA streams. The adjacently disclosed unit operations of drying and the use of bleaching clay further reinforce that Ghisalberti is only concerned with removing trace components that contribute to taste, odor, and perhaps color in the resultant CLA product. Such components are smaller, volatile components that are typically present in the CLA in amounts of parts per million. Deodorization is far different from enriching desired isomers in a CLA stream, and the Ghisalberti reference is completely silent regarding how to increase the content of desirable isomers in a CLA stream.

In addition to the complete lack of disclosure in the Ghisalberti reference of how to enrich (increase) desired isomers in a CLA stream, the Reaney et al. patent, U.S. Patent No. 6,420,577, undermines the Examiner's position that standard distillation means can be used to enrich desirable c9,t11 and t10,c12 isomers. Example 19 of

Reaney details a procedure in which fractional distillation was used to refine CLA. The refined CLA product contained a series of CLA isomers that reflected "the formation of undesirable CLA products of unknown biological activity." Col. 8, lines 3-7, emphasis added. The Reaney patent therefore concluded that "[d]istillation was not an appropriate method of refining CLA." Id. at lines 7-8.

Accordingly, the lack of any disclosure in Ghisalberti of how to enrich a CLA stream, coupled with the clear teaching in the Reaney patent that "distillation is not an appropriate method of refining the CLA," demonstrates that it would not have been obvious and/or predictable to one of skill in the art at the time of the claimed invention to use a fractionating column and heater to enrich desirable isomers in a CLA product stream. One of skill in the art, given the Reaney patent's teaching, as well as the Saebo patent's teaching that high temperature refining techniques lead to undesirable thermal rearrangements (see Saebo, U.S. Patent No. 6,410,761 at Col. 10, lines 31-35), would not have had any expectation that a CLA ester stream could be successfully enriched in desirable CLA isomers using a distillation apparatus containing a fractionating column, as required by the present claims.

The Examiner's citation to the Saebo reference in combination with Ghisalberti does not satisfy the deficiencies noted above. Saebo is apparently cited for its disclosure of a distillation pressure of 10^{-1} to 10^{-2} millibar. However, Saebo does not teach or suggest the use of a distillation apparatus containing a fractionating column and a heater operated at a temperature in the range of 240° C to 270° C, as recited in the claims. Accordingly, for all of the above reasons, it is submitted that the present

claims 1, 2 and 4-7 are not obvious in view of the combination of Ghisalberty in view of Saebo.

35 U.S.C. §103(a) Rejection Based on Saebo in view of Baltes et al. and Sachtler

Claims 8-20 have been rejected as being unpatentable over Saebo in view of Baltes et al. (U.S. 3,162,658), and further in view of Sachtler (U.S. 5,326,925). Claim 8 has been amended to recite that the distillation apparatus also comprises, in addition to a fractionating column, a heater operated at a temperature in the range of 240° C to 270° C. To the extent that the rejection is applied against claims 8-20, as amended, it is respectfully traversed.

Saebo discloses processes for preparing CLA, including distillation of the CLA using a molecular distillation plant at a vacuum of 10^{-1} to 10^{-2} millibar, and at a temperature of 190° C. According to Saebo, the advantage of using molecular distillation is the short time (less than 1 minute) at which the CLA is held at an elevated temperature. The emphasis on short exposure time is to avoid the known thermal instability and rearrangement of conjugated linoleic acids into undesirable CLA isomers.

Saebo does not disclose or suggest distillation using the presently claimed fractionating column and heater operating at a temperature of 240° C to 270° C, nor would it have been obvious and/or predictable to use a fractionating column, instead of the molecular distillation plant disclosed by Saebo, because as discussed above in connection with claims 1, 2 and 4-7, the Reaney patent clearly states that fractional distillation is not an appropriate method for refining CLA.

According to the Office Action, the Saebo article submitted as Exhibit A to the Rongione Affidavit, provides motivation to vary the temperature parameters to achieve the desired isomers. That one can vary temperature to achieve new isomers does not provide any guidance of how to increase the content of desirable c9,t11 and t10,c12 isomers in a CLA stream. Moreover, the Exhibit A reference clearly discloses that desirable isomers (t10, c12), undergo rearrangement into undesired isomers at temperatures of 220° C. Thus, one would not consider utilizing a distillation apparatus, such as the claimed fractionating column, operating at temperatures higher than 220° C, to enrich the content of desirable isomers, because of the known thermal rearrangement that occurs with such isomers at temperatures of 220° C. See March 13, 2009 Rongione Affidavit Under 37 CFR §1.132 at ¶5.

In view of Saebo's disclosure to use molecular distillation in order to avoid thermal rearrangement of desirable CLA isomers into undesirable isomers, and Reaney's disclosure that fractional distillation results in the formation of undesirable CLA products of unknown biological origin and is not an appropriate method for refining CLA, it is submitted that the presently claimed use of a fractionating column and heater to obtain a CLA stream enriched in desirable isomers would not have been obvious.

The Examiner's citation of Baltes et al. and Sachtler in combination with Saebo does not satisfy the deficiencies noted above with respect to Saebo. Baltes et al. merely discloses a process for the preparation of conjugated linoleic acids, and is completely silent with respect to a method of distilling conjugated linoleic acids. Thus, Baltes does not teach or suggest the use of a fractionating column to distill conjugated

linoleic acid esters or the use of a heater operating at a temperature of 240° C to 270° C, as now recited in claim 8. Nor would the use of such a fractionating column be obvious for the reasons recited above in connection with claims 1, 2 and 4-7.

Sachtler et al. is cited merely for allegedly disclosing a dual reaction system in an isomerization process. However, Sachtler does not relate to the preparation of conjugated linoleic acid esters and is completely silent with respect to a method for distilling a conjugated linoleic acid ester stream. Consequently, Sachtler does not satisfy the deficiencies noted in the proposed combination of Saebo with Baltes. Even if the references were combined as proposed, the combination does not teach or suggest the distillation method recited in amended claim 8, wherein the distillation of an ester stream containing conjugated linoleic acid esters is carried out in a distillation apparatus comprising a fractionating column and a heater operating at a temperature of 240° C to 270° C.

For all of the above reasons, it is submitted that the claims, as amended, are patentable over the art of record, and reconsideration of the application and allowance of the claims are respectfully requested.

The Commissioner is authorized to charge any necessary fees or credit any overpayment to Deposit Account No. 13-0017 in the name of McAndrews, Held & Malloy, Ltd.

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Respectfully submitted,

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